RENOVIS

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Special 510(k) Summary
as required by 21 CFR 807.92(a)
K140106

A) Submitted by: Renovis Surgical Technologies, Inc.
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Consultant: Sharyn Orton, Ph.D.
MEDIcept, Inc.
200 Homer Ave
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Date: February 28, 2014

B) Device Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Common Name: Intervertebral body fusion device

Proprietary Name: S128 Anterior Lumbar Interbody Fusion (ALIF) System

Device Class: Class II – 888.3080

Regulation and Product code: 888.3080, OVD - Intervertebral body fusion device

Classification panel: Orthopedic

C) Predicates:

- K131122 Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

D) Device Description:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is cleared under K131122. The S128 ALIF implants (cages) are to be used with the bone screws and anterior cover plate assembly and requires no additional supplementary fixation systems. The Renovis S128 ALIF System implants are available in a variety of sizes (widths, height, depths, and bone screw sizes; see below) to suit the individual pathology and anatomical conditions of the patient. The implants are manufactured from PEEK or additively manufactured and machined Titanium. The bone screws and cover plate

assembly are both manufactured from Titanium alloy. The PEEK markers are manufactured from Tantalum.

This Special 510(k) Premarket Notification is submitted for the additional offering of gamma sterilized S128 implants (PEEK cages; titanium cages, screws and cover plates).

E) Indications For Use:

The Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Renovis S128 ALIF System implants are to be used with autogenous bone graft.

Patients should be skeletally mature and have at least six months of non-operative treatment.

The Renovis S128 ALIF System is a stand-alone device and is intended to be used with the cover plate and screws provided and requires no additional supplementary fixation. The anterior cover plate must be utilized whenever the device is implanted using the bone screws provided. Should the physician choose to use fewer than the four screws provided, additional supplemental fixation cleared by the FDA for use in the lumbar spine must be used.

F) Substantial Equivalence Comparison and Discussion

	Renovis S128 ALIF System	Renovis S128 ALIF System K131122
Product code	OVD	
Implant Material (cages, cover plate, and screws)	PEEK (ZA-500) per ASTM F2026 Titanium alloy Ti-6Al-4V per ASTM F136	
PEEK marker material	Tantalum per ASTM F 560-08	
Dimensions (mm) A/P M/L H	 26, 28, 30 30, 34, 38 11 - 21	
Lordosis	7°, 12°	
Number of screws	4	
Screw Diameter (mm)	4.5, 5.	
Screw Length (mm)	20, 25, 30, 35	
Cover plate (mm)	8.3 x 22	
Provided sterile?	Yes - gamma	No

Conclusion

Based upon the same intended use, design, function, technology, and materials, the Renovis S128 ALIF System is substantially equivalent to the predicate devices and does not raise new issues of safety or effectiveness.

G) Performance Data

Implants are sterilized by ^{60}Co Gamma irradiation validated to a sterility assurance level (SAL) of 10^{-6} by selecting and substantiating a 25 kGy dose by the VDmax ^{25} method, according to ISO 11137-1. Titanium alloy components are not affected by gamma sterilization and/or aging. PEEK components were tested to an average dose of 200kGy and underwent accelerated aging to simulated 10 or more years. After aging the samples were tested, and the results did not show any significant difference between untreated PEEK and gamma treated and aged PEEK.

Packaging has been validated to maintain sterility for 3 years in compliance with ISO 11607-2 demonstrates compliance with accelerated aging simulation per ASTM F1980-7 and real time aging; and performance following distribution per ISTA 2A.

Conclusion

Gamma sterilization does not have a negative effect on Renovis S128 ALIF System implants.

H) Compliance with Design Controls

The results of design validation support that the Renovis S128 ALIF System is substantially equivalent to the predicate device and the offering of gamma irradiated implant components does not raise new issues of safety or effectiveness.

I) Compliance with Consensus Standards and FDA Guidance

Standards - Renovis complies with:

- ASTM F2026 Standard Specification for PEEK Polymers for Surgical Implant Applications
- ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, and
- ASTM F 560-08, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications
- ISO 11137-1: 2006: Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 11137-2:2006 Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
- ISO11607-2: 2006 Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980-07: 2007 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

- ASTM D4169:2009 Standard Practice for Performance Testing of Shipping Containers and Systems
- ISTA 2A, 2011 Partial-Simulation Performance Test Procedure: Packaged Products 150lb (68 kg) or Less

FDA guidance:

- Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA, August 2002
- Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, October 2007
- Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Review Guidance, April 1996
- Guidance for Industry and FDA Staff Spinal System 510(k)'s, May 2004 (for labeling language)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 27, 2014

Renovis Surgical Technologies, Incorporated
% Sharyn Orton, Ph.D.
MEDIcept, Incorporated
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K140106
Trade/Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: March 5, 2014
Received: March 7, 2014

Dear Dr. Orton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K140106

Device Name: Renovis S128 Anterior Lumbar Interbody Fusion (ALIF) System

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Prescription Use X (21 CFR 801, Subpart D)	AND/OR	Over-the-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of *CDRH, Office of Device Evaluation (ODE)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices